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8 UNITED STATES DISTRICT COURT  
9 SOUTHERN DISTRICT OF CALIFORNIA  
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11 ISIS PHARMACEUTICALS, INC., a  
12 Delaware Corporation,

13 Plaintiff,

14 v.

15 SANTARIS PHARMA A/S CORP., a  
16 Delaware Corporation, and  
17 SANTARIS PHARMA A/S, a Danish  
18 Corporation,

19 Defendants.  
20

21  
22 AND RELATED COUNTERCLAIMS.  
23  
24

Case No. 3:11-cv-2214-GPC-KSC

**ORDER GRANTING  
DEFENDANTS' MOTION TO  
DISMISS**

**(ECF NO. 252)**

21 After two rounds of summary judgment on the issue of whether their allegedly  
22 infringing activities fall within the "safe harbor" provided by 35 U.S.C. § 271(e)(1),  
23 defendants Santaris Pharma A/S Corp. and Santaris Pharma A/S (both, Defendants or  
24 Santaris) move to dismiss plaintiff Isis Pharmaceuticals, Inc.'s (Plaintiff or Isis) first  
25 amended complaint (FAC) to the extent that the FAC is premised on the sale or offer  
26 for sale of Isis's patented methods. (ECF No. 252-1.) Defendants' motion to dismiss  
27 has been fully briefed, (ECF Nos. 260, 267), and the Court finds it suitable for  
28 disposition without oral argument, see Civil Local Rule 7.1.d.1.

1 Plaintiff alleges infringement of three patents: 6,326,199 ('199 patent),  
2 6,066,500 ('500 patent), and 6,440,739 ('739 patent). The '199 patent claims methods  
3 of reacting certain "gapmer" or "gapped" oligonucleotide compounds in a cell. The  
4 '500 patent and the '739 patent each claim methods and compounds. The '500 patent  
5 claims a method for contacting cells or tissues in a laboratory dish with antisense  
6 compounds that inhibit the expression of the human beta catenin protein. The '739  
7 patent is similar to the '500 patent, except that it claims methods and compounds that  
8 affect a different protein: glioma-associated oncogene-2 (Gli2).

9 Plaintiff alleges the foregoing patents embody a "platform" technology that  
10 enables Plaintiff to design, evaluate, and develop candidate antisense compounds.  
11 Plaintiff alleges that Santaris sells these antisense drug discovery services and products  
12 to U.S. pharmaceutical companies in direct competition with Isis. Plaintiff alleges  
13 these sales are memorialized in commercial agreements with its pharmaceutical  
14 collaborators, pursuant to which Santaris agreed to transfer property and/or perform  
15 services for a certain price. Plaintiff alleges these sales and offers for sale occurred in  
16 the U.S., and that Santaris's sales and offers to sale have harmed Isis and the value of  
17 its patents.

18 A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) tests the  
19 sufficiency of a complaint. Navarro v. Block, 250 F.3d 729, 732 (9th Cir. 2001).  
20 Dismissal is warranted under Rule 12(b)(6) where the complaint lacks a cognizable  
21 legal theory. Robertson v. Dean Witter Reynolds, Inc., 749 F.2d 530, 534 (9th Cir.  
22 1984); see Neitzke v. Williams, 490 U.S. 319, 326 (1989) ("Rule 12(b)(6) authorizes  
23 a court to dismiss a claim on the basis of a dispositive issue of law."). Alternatively,  
24 a complaint may be dismissed where it presents a cognizable legal theory yet fails to  
25 plead essential facts under that theory. Robertson, 749 F.2d at 534.

26 In reviewing a motion to dismiss under Rule 12(b)(6), the court must assume the  
27 truth of all factual allegations and must construe all inferences from them in the light  
28 most favorable to the nonmoving party. Thompson v. Davis, 295 F.3d 890, 895 (9th

1 Cir. 2002); Cahill v. Liberty Mut. Ins. Co., 80 F.3d 336, 337-38 (9th Cir. 1996).

2 Here, the success of Defendants’ motion to dismiss turns largely on the legal  
3 question of whether the sale or offer for sale of a patented method may serve as a basis  
4 for infringement liability under 35 U.S.C. § 271(a).<sup>1</sup>

5 Defendants argue that, “under § 271(a), method claims can only be infringed by  
6 use, when the steps of the claims are performed—they cannot be infringed through a  
7 sale, or an offer for sale.” (ECF No. 252-1 at 6.) Defendants contend the “legislative  
8 history of § 271(a), Federal Circuit case law, and better-reasoned district court  
9 decisions compel this conclusion.” (Id.)

10 In response, Plaintiff argues Defendants’ position lacks merit because the “plain  
11 language of Section 271(a) could not be clearer.” (ECF No. 260 at 6.) Plaintiff thus  
12 argues that, because § 271(a) is unambiguous, Defendants err under the rules of  
13 statutory construction by resorting to legislative history to argue that the sale or offer  
14 for sale of a method claim does not constitute infringement under § 271(a). Plaintiff  
15 further argues that Defendants’ position is contrary to, or misapplies, relevant case law.

16 Section 271(a) provides: “Except as otherwise provided in this title, whoever  
17 without authority makes, uses, offers to sell, or sells any patented invention, within the  
18 United States or imports into the United States any patented invention during the term  
19 therefor, infringes the patent.”<sup>2</sup>

20 In construing § 271(a), the Federal Circuit has recognized that “the concept of  
21 ‘use’ of a patented method or process is fundamentally different from the use of a  
22 patented system or device.” NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282,

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24 <sup>1</sup> As will be discussed below, Defendants also move to dismiss Plaintiff’s allegation that  
25 Defendants infringed the ‘500 and ‘739 patents by entering into collaboration agreements with U.S.  
26 pharmaceutical companies because, at the time of contracting, neither of the gene targets that the ‘500  
and ‘739 patents were meant to affect (beta catenin and Gli2, respectively) had been identified by  
Defendants and their U.S. collaborators.

27 <sup>2</sup> “[I]nvention” means invention or discovery,” and “‘process’ means process, art or method,  
28 and includes a new use of a known process, machine, manufacture, composition of matter, or  
material.” 35 U.S.C. § 100(a) & (b). “Whoever invents or discovers any new and useful process,  
machine, manufacture, or composition of matter, or any new and useful improvement thereof, may  
obtain a patent therefor, subject to the conditions and requirements of this title.” Id. § 101.

1 1317 (Fed. Cir. 2005) (citing In re Kollar, 286 F.3d 1326, 1332 (Fed Cir. 2002)  
 2 (recognizing “the distinction between a claim to a product, device, or apparatus, all of  
 3 which are tangible items, and a claim to a process, which consists of a series of acts or  
 4 steps . . . . [A process] consists of doing something, and therefore has to be carried out  
 5 or performed.”); Joy Techs, Inc. v. Flakt, Inc., 6 F.3d 770, 773 (Fed Cir. 1993) (“The  
 6 law is unequivocal that the sale of equipment to perform a process is not a sale of the  
 7 process within the meaning of section 271(a).”)); Quanta Computer, Inc. v. LG  
 8 Electronics, Inc., 553 U.S. 617, 628 (2008) (observing, in the context of patent  
 9 exhaustion, that “a patented method may not be sold in the same way as an article or  
 10 device”).

11 The Federal Circuit has also recognized that “[i]t is well established that a  
 12 patent for a method or process is not infringed unless all steps or stages of the claimed  
 13 process are utilized.” NTP, 418 F.3d at 1318 (quoting Roberts Dairy Co. v. United  
 14 States, 530 F.2d 1342, 1354 (1976). “Because a process is nothing more than the  
 15 sequence of actions of which it is comprised, the use of a process necessarily involves  
 16 doing or performing each of the steps recited.” NTP, 418 F.3d at 1318. Thus, when  
 17 presented with a situation where some steps of a patented process occurred outside the  
 18 United States, the Federal Circuit held “that a process cannot be used ‘within’ the  
 19 United States as required by section 271(a) unless each of the steps is performed within  
 20 this country.” Id. And, only if each of the steps was performed within the United  
 21 States, would the process patent be infringed. See id.

22 The Federal Circuit then went on to address the issue that is directly relevant to  
 23 the instant motion: “the issue of whether a method claim may be infringed by selling  
 24 or offering to sell within the meaning of section 271(a).” Id.

25 Explaining that neither “sale” or “offers to sale” as used in § 271(a) are defined  
 26 by statute, the Federal Circuit began its analysis with these terms. Id. at 1319.  
 27 Observing that it had, in the past, used dictionaries and the Uniform Commercial Code  
 28 to define the phrase “sale for importation” in connection with an International Trade

Commission case, the Federal Circuit turned to Black’s Law Dictionary to define the term “sale” as used in § 271(a). Id. Using the Black’s definition, the court concluded “the ordinary meaning of a sale includes the concept of a transfer of title or property,” and that it was thus “difficult to envision what property is transferred merely by one party performing the steps of a method claim in exchange for payment by another party.” Id. “[P]erformance of a method does not necessarily require anything that is capable of being transferred.” Id.

Recognizing that § 271(a) “was not meant to change the [common] law of infringement,” and relying on several pieces of legislative history, the Federal Circuit observed that “Congress has consistently expressed the view that it understands infringement of method claims under section 271(a) to be limited to use.”<sup>3</sup> Id. at 1320; see also Joy Techs., 6 F.3d at 775 (“A method claim is directly infringed only by one practicing the patented method.”).

Given Congress’s expressed views, the Federal Circuit reiterated the Supreme Court’s cautionary edict with regard to patent protection: “We would require a clear and certain signal from Congress before approving the position of a litigant who . . . argues that the beachhead of [patent] privilege is wider, and the area of public use narrower, than courts had perviously though.” NTP, 418 F.3d at 1320 (quoting Deepsouth Packing Co., Inc. v. Laitram Corp., 406 U.S. 518, 531 (1972), superseded on other grounds by statute, 35 U.S.C. § 271(f)). With regard to the question before it, the Federal Circuit concluded: “The indication we have from Congress on

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<sup>3</sup> The Court rejects Plaintiff’s argument that, under the rules of statutory construction, consideration of the legislative history underlying § 271(a) is inappropriate. The Federal Circuit expressly found the issue of whether a sale of a claimed method could serve as a basis for infringement liability to be an issue of first impression. NTP, 418 F.3d at 1318. The Federal Circuit then noted that § 271(a) “does not define ‘sell’ or ‘offers to sell,’ nor does the statute specify which infringing acts apply to which types of claims.” Id. at 1319. On that basis, the Federal Circuit examined the ordinary meaning of these terms before going on to consider Congress’s understanding of whether infringement of method claims under § 271(a) is limited to use. The Federal Circuit did all of this after recognizing that, in interpreting statutes, courts “give the words of a statute their ordinary, contemporary, common meaning, absent an indication Congress intended them to bear some different import.” NTP, 418 F.3d at 1314-15 (quoting Williams v. Taylor, 529 U.S. 420, 431 (2000)). As such, this Court finds no basis in law or fact to reject the Federal Circuit’s consideration of Congress’s understanding of § 271(a).

1 infringement by selling or offering to sell method claims shows that it believes the  
2 beachhead is narrow.” NTP, 418 F.3d at 1320.

3 Then, an inch away from deciding the broader question of whether a method  
4 claim may be infringed under the “sells” and “offer to sell” prongs of § 271(a), the  
5 Federal Circuit concluded that, based on the facts before it, the “performance of at least  
6 some of the recited steps of the asserted method claims as a service for [the accused  
7 infringer’s] customers cannot be considered to be selling or offering to sell the  
8 invention covered by the asserted method claims.” NTP, 418 F.3d at 1320-21.

9 Following NTP, several district courts have concluded that a patent holder may  
10 not base its infringement claims on the sale or offer for sale of a patented method. See  
11 W.L. Gore & Assocs., Inc. v. Medtronic, Inc., 874 F. Supp. 2d 526, 544-45 (E.D. Va.  
12 2012) (observing that “the Federal Circuit appears to have concluded that [the ‘sale’  
13 or ‘offer for sale’] prong does not apply to method claims”) (citing NTP, 418 F.3d at  
14 1321; Zoltek Corp. v. United States, 672 F.3d 1309, 1322 (Fed. Cir. 2012)); see also  
15 In re Bill of Lading Transmission & Processing Sys. Patent Litig., 695 F. Supp. 2d 680,  
16 688 (S.D. Ohio 2010) (“[T]his Court is persuaded that ‘offer to sell’ liability does not  
17 apply to claims of infringement of a method patent.”); see also Transocean Offshore  
18 Deepwater Drilling, Inc. v. GlobalSantaFe Corp., 400 F. Supp. 2d 998, 1011 (S.D. Tex.  
19 2005) (concluding § 271(a)’s prohibition against “offers to sell” is not applicable where  
20 the offer was to perform patented methods for compensation); see also Ricoh Co., Ltd.  
21 v. Quanta Computer, Inc., 579 F. Supp. 2d 1110, 1123 (W.D. Wis. 2007) (granting  
22 accused infringers’ motion for summary judgment because plaintiff had not cited any  
23 authority or offered any argument “why anything other than defendants’ use of the  
24 accused devices incorporating the method should constitute infringement under §  
25 271(a)”), reversed in part on other grounds, 550 F.3d 1325; but see CLS Bank Int’l v.  
26 Alice Corp. Pty. Ltd., 667 F. Supp. 2d 29, 36-37 (D.D.C. 2009) (ignoring Federal  
27 Circuit’s analysis of § 271(a) in NTP, and relying on Supreme Court’s analysis in  
28 Quanta, 553 U.S. 617, regarding patent exhaustion context, to conclude “the Court sees

1 no persuasive reason why a method claim could not also be sold for infringement  
2 purposes”); WesternGeco LLC v. ION Geophysical Corp., 869 F. Supp. 2d 793, 798-99  
3 (S.D. Tex. 2012) (relying on analysis in CLS Bank to reach same conclusion); Optigen,  
4 LLC v. Int’l Genetics, Inc., 777 F. Supp. 2d 390, 403 (N.D.N.Y. 2011) (same).

5 Here, Plaintiff alleges that Santaris has agreed to perform the steps of Isis’s  
6 claimed methods—a “platform” technology—as a service for Santaris’s U.S.  
7 customers. Plaintiff alleges the steps of Isis’s claimed methods are performed without  
8 the United States, but that the sale and/or offer for sale of these services occurred  
9 within the United States. Given clear precedent that a method patent may only be  
10 infringed when each of its steps are performed within the United States, and given the  
11 Federal Circuit’s near categorical rejection of claims for infringement of a method  
12 patent under the “sale” and “offers to sale” prongs of § 271(a), this Court concludes  
13 that, to the extent Plaintiff’s infringement claims against Defendants are based on  
14 Defendants’ infringement of Plaintiff’s method claims through the sale or offer for sale  
15 of such claims, Plaintiff’s infringement claims must be dismissed. The Court thus  
16 proceeds to Defendants’ second basis for dismissal.

17 Defendants also move to dismiss Plaintiff’s allegation that Defendants infringed  
18 the ‘500 and ‘739 patents by entering into collaboration agreements with U.S.  
19 pharmaceutical companies because, at the time of contracting, neither of the gene  
20 targets that the ‘500 and ‘739 patents were meant to affect (beta catenin and Gli2,  
21 respectively) had been identified by Defendants and their U.S. collaborators.  
22 Defendants assert that, “according to Isis’s FAC, at the time of the execution of the  
23 Enzon agreement, at best, Santaris had allegedly offered for sale and sold to Enzon as-  
24 yet-to-be identified antisense compounds and method for inhibiting the expression of  
25 said unidentified compounds.” (ECF No. 252-1 at 18.) Defendants assert that such  
26 offers for sales and sales should be dismissed because they did not, by definition,  
27 “possess[] every limitation of the asserted claims.” [*Id.* (citing Transocean Offshore  
28 Deepwater Drilling v. Maersk Drilling USA, Inc., 699 F.3d 1340, 1357 (Fed. Cir.

2012).]

In response, Plaintiff does not dispute that the targets affected by the compounds claimed in the ‘500 and ‘739 patents were not identified in the collaboration agreements at the time of execution and that, therefore, Plaintiff’s infringement allegations are deficient to the extent that they rely on the execution of the collaboration agreements as a basis for infringement of the ‘500 and ‘739 patents. Instead, Plaintiff argues that, for pleading purposes, Defendants have sufficient notice of Plaintiff’s allegation regarding the sale and offer for sale of the compounds claimed in the ‘500 and ‘739 patents. Plaintiff argues that, in response to one of Defendants’ interrogatories, Plaintiff “outlined Santaris’s infringing acts of ‘offering for sale’ and ‘selling’ at a time when the gene targets of the ‘500 and ‘739 Patents were newly identified.”

As set forth above, the sale or offer for sale of a patented invention constitutes infringement under § 271(a). But, in order for a “patented invention” to be infringed through the “sales” or “offers to sale” prongs of § 271(a), whatever is sold or offered for sale must “possess[] every limitation of the asserted claims.” Transocean Offshore, 699 F.3d 1340, 1357 (Fed. Cir. 2012); see also Rotec Indus. Inc. v. Mitsubishi Corp., 215 F.3d 1246, 1253 n.2 (Fed. Cir. 2000) (“[O]ne may not be held liable under § 271(a) for ‘making’ or ‘selling’ less than a complete invention.”).

The Court finds Plaintiff has failed to plead sufficient facts to state a claim for infringement of the ‘500 and ‘739 patents’ compound claims based on Santaris’s entering into the Enzon agreement, which, at the time of contracting, did not include

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1 all limitations of the claims in issue. In other words, Plaintiff has failed to plead  
2 sufficient facts demonstrating that Santaris's entering into the Enzon agreement  
3 constituted the sale or offer for sale of the compounds claimed in the '500 and '739  
4 patents.

5 For the foregoing reasons, **IT IS HEREBY ORDERED** that Defendants'  
6 motion to dismiss, (ECF No. 252), is **GRANTED**.

7 DATED: June 4, 2014

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9 HON. GONZALO P. CURIEL  
10 United States District Judge  
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